IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

YVONNE BARNES, PATRICIA DEAN, ANTONIO MORRIS, and BERNADETTE BOGDANOVS, individually and on behalf of all others similarly situated,	)	
Plaintiffs,	)	
vs.	)	**Case No. 21 C 6191**
UNILEVER UNITED STATES INC.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

Four plaintiffs—Yvonne Barnes, Patricia Dean, Antonio Morris, and Bernadette Bogdanovs—filed suit against Unilever United States Inc. Unilever manufactures and distributes Suave antiperspirant products. The plaintiffs (which the Court will collectively call Barnes) allege that the products contain benzene, a carcinogen, which was not disclosed in the labeling and renders the products adulterated.

Before Barnes filed her consolidated amended complaint combining this case with Case No. 22 C 3143, *Bogdanovs v. Unilever United States Inc.*, Unilever moved to dismiss an earlier version of Barnes's complaint for lack of standing and failure to state a claim. The Court denied the motion to dismiss for lack of standing, except with respect to Barnes's request for injunctive relief, and granted in part and denied in part the motion to dismiss for failure to state a claim. *See Barnes v. Unilever U.S. Inc.*, No. 21 C 6191, 2022 WL 2915629, at *2–3 (N.D. Ill. July 24, 2022).

In her consolidated amended complaint, Barnes asserts claims on behalf of nationwide, multi-state, and Illinois-based and California-based classes under the state consumer fraud acts of the various states (Count 1); the Illinois Consumer Fraud and Deceptive Business Practices Act (ICFA) (Count 2); the California Unfair Competition Law (CUCL) (Count 3); the California False Advertising Law (CFAL) (Count 4); the California Consumer Legal Remedies Act (CCLRA) (Count 5); and for unjust enrichment (Count 6). Unilever has again moved to dismiss for failure to state a claim. For the reasons stated below, the Court denies the motion, except to the extent Barnes's claims are based on Unilever's alleged omission of benzene in its labeling.

Background

Unilever sells Suave-brand deodorant and antiperspirant aerosol and spray products at retail stores throughout the United States. According to the amended complaint, deodorants and antiperspirants are considered, respectively, cosmetics and over-the-counter (OTC) drugs by the U.S. Food and Drug Administration (FDA). OTC drugs are required by federal law to comply with current Good Manufacturing Practices (cGMPs) established by the FDA "to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a)(2)(B).

In November 2021, Valisure, the operator of an analytical laboratory, tested for benzene in thirty brands of antiperspirant aerosol products. Valisure detected benzene in most of the 108 batches tested. In Unilever's products, Valisure's testing allegedly measured benzene concentrations from 0.97 to 5.21 ppm. Unilever had discontinued

the product line in October 2021 and voluntarily recalled the products in March 2022.

Barnes alleges that benzene is a carcinogen that Unilever's products "are not designed to contain." Am. Compl. ¶ 58. In June 2017, the FDA issued a guidance document stating that benzene "should not be employed in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity or [its] deleterious environmental effect." Q3C - Tables and List Guidance for Industry, 2017 WL 3491767, at *2. "If [its] use is unavoidable in order to produce a drug product with a significant therapeutic advance, then [its] levels should be restricted" to 2 ppm "unless otherwise justified." *Id.* Barnes alleges that "because benzene is not a requisite component of manufacturing or packaging body sprays," its use in Unilever's products "is not unavoidable." Am. Compl. ¶ 56. Barnes further alleges that the presence of benzene "resulted from Defendant's failure to comply with cGMPs" and renders Unilever's products "adulterated" under federal and state law. *Id.* ¶ 75.

Benzene is not listed as either an active or inactive ingredient on Unilever's products' labels. The labels also do not warn of the risk of benzene exposure. Barnes alleges that these omissions mislead consumers about the safety of the products. The amended complaint also identifies several statements regarding product safety and testing from Unilever's website that Barnes alleges are false and misleading. Had Barnes known that the products contained or may contain benzene, Barnes alleges that she would not have purchased the products or would have paid less for them.

Discussion

Barnes asserts claims under the state consumer fraud acts of various states, including the ICFA, CUCL, CFAL, and CCLRA specifically, and for unjust enrichment.

Unilever has moved to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim.

In deciding a motion to dismiss for failure to state a claim, the court must accept as true all well-pleaded factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor. *See NewSpin Sports, LLC v. Arrow Elecs., Inc.*, 910 F.3d 293, 299 (7th Cir. 2019). To survive a motion to dismiss, a plaintiff must allege "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Bissessur v. Ind. Univ. Bd. of Trs.*, 581 F.3d 599, 602 (7th Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

A. Consumer fraud claims

Unilever contends that all Barnes's claims are based on her allegations that Unilever engaged in deceptive practices by omitting the presence of benzene in its products. Barnes contends that she has also asserted claims based on unfair practices and affirmative misrepresentations.

1. Alleged unfair practices

"The Supreme Court of Illinois has held that recovery under the Consumer Fraud Act 'may be had for unfair as well as deceptive conduct.'" *Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Fin. Servs., Inc.*, 536 F.3d 663, 669 (7th Cir. 2008) (quoting *Robinson v. Toyota Motor Credit Corp.*, 201 Ill. 2d 403, 416, 775 N.E.2d 951, 960 (2002)). Deceptive conduct and unfair conduct "are separate categories," and an ICFA claim "may be premised on either (or both)." *Vanzant v. Hill's Pet Nutrition, Inc.*, 934 F.3d 730, 738 (7th Cir. 2019). Similarly, "the UCL creates 'three varieties of unfair competition—acts or practices which are unlawful, or unfair, or fraudulent.'" *Wilson v.*

Hewlett-Packard Co., 668 F.3d 1136, 1140 (9th Cir. 2012) (quoting *Cel–Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 180, 973 P.2d 527, 540 (1999)).

Barnes's amended complaint is not as limited as Unilever contends; it includes claims premised on allegations of unfair practices. As the Court held on Unilever's first motion to dismiss, "allegations that Unilever put adulterated and therefore dangerous products into the marketplace without adequate testing or screening—which is the gist of Barnes's claim—are sufficient to state a claim for an unfair practice violative of the ICFA." *Barnes*, 2022 WL 2915629, at *3. Similarly, such allegations can form the basis of a CUCL claim. *See Wilson*, 668 F.3d at 1140 ("The California Supreme Court has held that the UCL's 'coverage is sweeping, embracing anything that can properly be called a business practice and that at the same time is forbidden by law.'" (quoting *Cel–Tech*, 20 Cal. 4th at 180, 973 P.2d at 539)).

Although Unilever argues that Barnes's earlier complaint "has been superseded," Def.'s Reply Br. at 10, Unilever does not point to any changes to the complaint that would dictate a different result. Instead, Unilever emphasizes Barnes's misrepresentations and omissions allegations from the operative complaint, without addressing Barnes's allegations that Unilever sold adulterated products. *See* Am. Compl. ¶¶ 62-75 (explaining how the products are adulterated and illegal to sell), ¶ 83 ("As a seller of an OTC drug product, Defendant had and has a duty to ensure that its Products did not and do not contain excessive (or any) level of benzene, including through regular testing, especially before . . . injecting [the products] into the stream of commerce for consumers to use on their bodies.").

Unilever concedes that Barnes alleges the factual basis of an unfair practices claim—namely, that Unilever sold adulterated products—but asserts that Barnes "does not purport to state a separate claim of unfairness on that ground." Def.'s Reply Br. at 10. The Court disagrees with this interpretation of the operative complaint, and, in any event, "[t]he Federal Rules of Civil Procedure do not require a plaintiff to plead legal theories." *Chessie Logistics Co. v. Krinos Holdings, Inc.*, 867 F.3d 852, 859 (7th Cir. 2017) (internal quotation marks omitted).

Unilever argues for the first time in reply that Barnes's allegations do not satisfy the elements of an unfair practices claim. "[A]rguments raised for the first time in a reply brief are waived." *Williams v. Bd. of Educ. of City of Chi.*, 982 F.3d 495, 507 n.30 (7th Cir. 2020). Even if the argument were not forfeited, Barnes has sufficiently alleged an unfair practices claim, as the Court held on the first motion to dismiss. *See Barnes*, 2022 WL 2915629, at *3. Barnes's "allegations of unfair practices meet the federal notice-pleading standards because they claim that [Unilever] engaged in unfair conduct and aver facts that, if proven, make relief more than merely speculative." *Benson v. Fannie May Confections Brands, Inc.*, 944 F.3d 639, 647 (7th Cir. 2019) (alterations accepted) (internal quotation marks omitted).

"To determine whether a practice is unfair, Illinois courts consider three factors: whether it offends public policy; is immoral, unethical, oppressive, or unscrupulous; or causes substantial injury to consumers." *Vanzant*, 934 F.3d at 738–39 (internal quotation marks omitted). "A plaintiff need not satisfy all three factors; 'a practice may be unfair because of the degree to which it meets one of the criteria or because to a lesser extent it meets all three.'" *Id.* at 739 (alterations accepted) (quoting *Robinson*,

201 Ill. 2d at 418, 775 N.E.2d at 961). As for the CUCL, "[u]nder the UCL's unfairness prong, courts consider either: (1) whether the challenged conduct is tethered to any underlying constitutional, statutory or regulatory provision, or that it threatens an incipient violation of an antitrust law, or violates the policy or spirit of an antitrust law; (2) whether the practice is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers; or (3) whether the practice's impact on the victim outweighs the reasons, justifications and motives of the alleged wrongdoer." *Doe v. CVS Pharmacy, Inc.*, 982 F.3d 1204, 1214–15 (9th Cir. 2020) (citations omitted) (internal quotation marks omitted).

Barnes alleges that Unilever's conduct violates the cGMPs, which would offend public policy. *See Drs. Direct Ins., Inc. v. Bochenek*, 2015 IL App (1st) 142919, ¶ 34, 38 N.E.3d 116, 126 (observing that when determining whether a practice is unfair, courts consider "whether it offends public policy 'as it has been established by statutes, the common law, or otherwise'" (quoting *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 n.5 (1972))); *Newman v. Metro. Life Ins. Co.*, 885 F.3d 992, 1002 (7th Cir. 2018) (holding that the defendant's alleged conduct offended Illinois's public policy where it violated a state statute and state administrative rule).

Similarly, Barnes's allegations that Unilever violated California's Sherman Act by selling adulterated drugs are sufficient to allege that the practices are "unlawful" and "unfair" under the CUCL. *See Friedman v. AARP, Inc.*, 855 F.3d 1047, 1052 (9th Cir. 2017) ("With respect to the unlawful prong of [the CUCL], it is clear that 'virtually any state, federal, or local law can serve as the predicate.'" (quoting *People ex rel. Lockyer v. Fremont Life Ins. Co.*, 104 Cal. App. 4th 508, 515, 128 Cal. Rptr. 2d 463, 469

(2002))); *Backus v. Gen. Mills, Inc.*, 122 F. Supp. 3d 909, 929–930 (N.D. Cal. 2015) (holding that the plaintiff's allegations that the defendant sold adulterated food in violation of California's Sherman Act, and thus also in violation of the "public policy of prohibiting the sale of adulterated food," were sufficient to state CUCL claims for "unlawful" and "unfair" practices).

In contending that Barnes has not satisfied the elements of an unfair practices claim, Unilever primarily focuses on the "substantial injury" requirement. Specifically, Unilever asserts that Barnes could "reasonably have avoided" the injury by purchasing other antiperspirants. Def.'s Reply Br. at 12 (quoting *Batson v. Live Nation Entm't, Inc.*, 746 F.3d 827, 830 (7th Cir. 2014)). But Barnes contends that testing has revealed that many antiperspirants contain benzene. Because Barnes alleges that she cannot perform benzene testing herself necessary to avoid contaminated antiperspirants, she has sufficiently alleged that she lacks "meaningful choice." *Robinson*, 201 Ill. 2d at 419, 775 N.E.2d at 962.

In sum, Barnes has stated viable unfair practices claims under the ICFA and CUCL.

2. Alleged deceptive practices

Barnes's amended complaint also identifies deceptive practices in the form of alleged affirmative misrepresentations, not simply alleged omissions. Barnes points to several statements made on Unilever's website about safety that she alleges are false. *See, e.g.*, Am. Compl. ¶ 94(d) ("All Suave formulas are safe to use and meet the highest global standards in safety and quality;"), ¶ 94(h) ("[R]egulatory assessment is conducted to ensure that our products, their ingredients, how they are manufactured

and labeled comply with all federal and state laws . . . .") (alterations accepted) (internal quotation marks omitted).

Unilever contends that these allegations do not satisfy Federal Rule of Civil Procedure 9(b) because Barnes did not allege with particularity that the statements are false.[1] This contention lacks merit. Barnes has sufficiently alleged that the website's safety statements are false via her allegations that Unilever does not conduct safety testing required by federal law. *See, e.g.*, Am. Compl. ¶ 83 ("[B]ased on Valisure's testing results set forth above, Defendant made no reasonable effort to test its Products for benzene or other impurities."); ¶ 100 ("If Defendant had not routinely disregarded the FDA's cGMPs, or had fulfilled their quality assurance obligations, Defendant would have identified the presence of the benzene contaminant through routine and required testing."). These allegations of falsity are sufficient under Rule 9(b). *See Vincent v. City Colleges of Chicago*, 485 F.3d 919, 925 (7th Cir. 2007) (holding that "[t]he complaint [wa]s sufficient" where it "allege[d] precisely the statement . . . that is asserted to be false, and the exact reason . . . why the statement was false").

3. Actual damages

Unilever contends that Barnes's claims must be dismissed because she has not alleged that she suffered actual damages, which Unilever argues is a required element of her claims.

"[A]ctual loss may occur if the seller's deception deprives the plaintiff of 'the

[1] In reply, Unilever additionally argues that Barnes's allegations do not satisfy Rule 9(b) because she does not allege when she saw the website statements. Because Unilever failed to raise this argument until its reply, it is forfeited. *See Williams*, 982 F.3d at 507 n.30 ("[A]rguments raised for the first time in a reply brief are waived.").

benefit of her bargain' by causing her to pay 'more than the actual value of the property.'" *Kim v. Carter's Inc.*, 598 F.3d 362, 365 (7th Cir. 2010) (quoting *Mulligan v. QVC, Inc.*, 382 Ill. App. 3d 620, 628, 888 N.E.2d 1190, 1197–98 (2008)); *see also Miller v. William Chevrolet/GEO, Inc.*, 326 Ill. App. 3d 642, 653, 762 N.E.2d 1, 10 (2001) ("Illinois courts have generally allowed damages claims based on diminished value of a product regardless of whether it has yet malfunctioned, provided the product contains a manifested defect or current condition affecting value."); *Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1104–05 (9th Cir. 2013) (holding that "to allege an economic injury under the UCL and FAL," the plaintiff need only allege that "he or she would not have bought the product but for the misrepresentation" or would have paid less, rejecting the defendant's argument that the plaintiff must "plead how much he would have paid for the merchandise had he known its true market value" (quoting *Kwikset Corp. v. Superior Ct.*, 51 Cal. 4th 310, 330, 246 P.3d 877, 890 (2011))), *as amended on denial of reh'g and reh'g en banc* (July 8, 2013). Barnes has sufficiently alleged actual damages by alleging that she "paid a higher price" because the products were "something less than [she] expected." *Vanzant*, 934 F.3d at 739; *see, e.g.*, Am. Compl. ¶ 163 ("Had they been aware of the true nature of the Products, Plaintiffs and Class Members either would have paid less for the Products or would not have purchased them at all.").

Unilever also argues that Barnes has not alleged that the specific products she purchased were contaminated. As the Court ruled in denying Unilever's first motion to dismiss, it is irrelevant if only some of the products were contaminated because "Barnes's theory of injury holds water even if based on the proposition that she would not have purchased the product had she known of the risk it contained benzene."

Barnes, 2022 WL 2915629, at *1 n.1. This is particularly so in view of the fact that benzene is contended to be a carcinogen and a substance that lingers in the human body, affecting several organs and "causing cells not to work correctly." Am. Compl. ¶ 32.

B. Preemption

In seeking dismissal, Unilever's primary contention is that all of Barnes's claims are expressly preempted under federal law. A provision of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 379r(a), prohibits states from establishing any requirement for OTC drugs "that is different from or in addition to, or that is otherwise not identical with, a requirement under" the FDCA. "Preemption . . . is an affirmative defense upon which the defendants bear the burden of proof." *Benson*, 944 F.3d at 645 (internal quotation marks omitted). The Court next analyzes whether Barnes's allegations of unfair practices and deceptive practices are preempted.

1. Unfair practices claims

In *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), the Seventh Circuit analyzed a similar express preemption provision relating to medical devices that prohibits any state from establishing any requirement "which is different from, or in addition to, any requirement applicable under" the FDCA. *Id.* at 550 (quoting 21 U.S.C. § 360k(a)).[2] The Seventh Circuit held that the provision "protects a medical device

[2] Unlike 21 U.S.C. § 360k(a), 21 U.S.C. § 379r(e) expressly does not preempt "the product liability law of any State." *See Wyeth v. Levine*, 555 U.S. 555, 575 n.8 (2009) ("In 1997, Congress pre-empted certain state requirements concerning over-the-counter medications and cosmetics but expressly preserved product liability actions."). But this difference is not relevant for present purposes because Barnes does not bring any product liability claims.

manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law." *Id.* at 552. In other words, where "both state and federal requirements [are] to the same effect," then "state law is parallel to federal law," and the state law claims are not expressly preempted by the provision. *Id.* (alterations accepted); *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 448 (2005) ("[A] state cause of action that seeks to enforce a federal requirement does not impose a requirement that is 'different from, or in addition to,' requirements under federal law.") (internal quotation marks omitted). The Seventh Circuit also rejected the defendants' argument that a "plaintiff must allege and prove a violation of a 'concrete, device-specific' federal regulation," holding instead that violations of "more general requirements," such as cGMPs, can support a parallel state law claim. *Id.* at 554–56.

In this case, Barnes alleges that Unilever has violated federal law. In particular, Barnes alleges that Unilever failed to comply with the cGMPs applicable to OTC drugs and accordingly sold "adulterated" products in violation of 21 U.S.C. § 331(a). *See* 21 U.S.C. § 351(a)(2)(B) (establishing that drugs not produced in compliance with cGMPs "shall be deemed adulterated"). Barnes further alleges that Unilever violated the Illinois Food, Drug and Cosmetic Act, which contains the same definition of "adulterated." *See* 410 Ill. Comp. Stat. 620/14. Barnes's unfair practices claims are accordingly parallel to federal law under *Bausch* because the claims do not impose any requirements that differ from federal law. Therefore, Barnes's unfair practices claims are not preempted under 21 U.S.C. § 379r(a).

In reply, Unilever provides two additional arguments for preemption of Barnes's

unfair practices claims. Both are unavailing. First, Unilever contends that because the cGMPs do not mention benzene specifically, any enforcement of the FDA's guidance on benzene would "impose a manufacturing requirement on Unilever that is 'in addition to' or 'different from' federal requirements." Def.'s Reply Br. at 5. But Barnes alleges that Unilever failed to comply with cGMPs and that the presence of benzene "resulted from [Unilever]'s failure to comply with cGMPs." Am. Compl. ¶ 75. Unilever does not contest that cGMPs are legally binding. *See* 21 C.F.R. § 330.1(a) (stating that any product not "manufactured in compliance with current good manufacturing practices" "is liable to regulatory action"); *Bausch*, 630 F.3d at 555 (holding that "federal law is clear" that cGMPs applicable to medical devices "are legally binding requirements"). Thus, the FDA's benzene guidance supports Barnes's allegations, but Barnes's unfair practices claims do not rely on violations of the FDA's guidance.

Second, Unilever argues that although Barnes "'must be suing for conduct that violates the FDCA to avoid express preemption, [she] must not be suing because the conduct violates the FDCA,' or else the claims are impliedly preempted." Def.'s Reply Br. at 5 (alterations accepted) (quoting *Vincent v. Medtronic, Inc.*, 221 F. Supp. 3d 1005, 1009 (N.D. Ill. 2016)). "[S]tate-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). The Supreme Court held in *Buckman* that the plaintiffs' suit alleging that the defendants made false statements to the FDA during the approval process of a medical device was impliedly preempted. *Id.* at 348–53. In *Bausch*, the Seventh Circuit distinguished "'fraud-on-the-agency' claims, *i.e.*, claims not related to a field of law that states had traditionally occupied, from claims based on state

law tort principles." *Bausch*, 630 F.3d at 557. The Seventh Circuit explained that "[w]hile there may not be a 'traditional state tort law' claim for an 'adulterated' product in so many words, the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products" and "goes a long way toward showing that the manufacturer breached a duty under state law toward the patient." *Id.*

Similarly, in this case, Barnes's unfair practices ICFA and CUCL claims, resting on her allegation that Unilever sold adulterated products, is not a claim that Unilever committed fraud against the FDA. Rather, it is a claim that Unilever breached a duty to consumers under the ICFA and CUCL. Unlike in *Buckman*, where "the fraud claims exist[ed] solely by virtue of the FDCA disclosure requirements," Barnes's unfair practices claims "ar[ise] from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." *Buckman*, 531 U.S. at 352–53 (2001); *see also Booker v. E.T. Browne Drug Co.*, No. 20 C 3166 (PMH), 2021 WL 4340489, at *7 (S.D.N.Y. Sept. 23, 2021) (holding that the plaintiffs' claims that a product did not perform as advertised were not preempted because, though the claims "f[ell] squarely within the realm of conduct that would violate the FDCA," they did not "rely on the FDCA for their existence" as they were "of a vintage that would exist under New York State law even if the FDCA had never been enacted").

Vincent, cited by Unilever, is inapposite. In that case, the court held that the plaintiff's claims "based solely on [the defendant]'s noncompliance with the FDA's supplemental premarket approval procedures . . . are impliedly preempted." *Vincent*,

221 F. Supp. 3d at 1011. But the court specifically noted that the plaintiff "d[id] not allege that [the defendant] violated any federal regulations in designing, manufacturing, or labeling." *Id.* at 1010. In this case, Barnes does allege violations of federal manufacturing regulations. *Vincent* does not suggest that such allegations are impliedly preempted.

2. Deceptive practices claims

A different result is warranted for Barnes's deceptive practices claims to the extent they are based on alleged omissions. Barnes alleges that Unilever's failure to disclose the presence of benzene as either an active or inactive ingredient on its products' labels was misleading. Unilever contends that federal law only requires it to disclose intended ingredients—which benzene, it says, was not. Thus, according to Unilever, Barnes's deceptive practices claims seek to impose a different, additional requirement and for that reason they are preempted under 21 U.S.C. § 379r(a). "The critical question . . . is therefore what requirements the federal law imposes on the labeling of" unintended ingredients, such as benzene. *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011).

FDA regulations for the labeling of OTC drugs are found in part 201. An OTC drug label must list the product's "active" and "inactive ingredients." 21 C.F.R. § 201.66(c). "Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans." 21 C.F.R. § 201.66(b)(2). An "[i]nactive ingredient" is "any component other than an active ingredient." 21 C.F.R. § 201.66(b)(8). Part 201 does not define

"component," but "component" is defined in part 210, which regulates drug manufacturing. "Component means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product." 21 C.F.R. § 210.3(b)(3). Accordingly, FDA regulations require Unilever to list only "ingredient[s] intended for use" in its products, not unintended contaminants such as benzene. *See Truss v. Bayer Healthcare Pharms. Inc.*, No. 21 CV 9845 (VB), 2022 WL 16951538, at *4 (S.D.N.Y. Nov. 15, 2022) (interpreting the same regulations to not require the disclosure of "degradation byproducts" that the "plaintiffs d[id] not allege defendants manufactured the Product to contain").

Barnes's contention that "component" should be interpretated more broadly is unpersuasive. Barnes relies on 21 C.F.R. § 210.3(b), which states that "[t]he following definitions of terms apply to this part and to parts 211, 225, and 226 of this chapter." Barnes implicitly contends that, had the FDA intended the definition of "component" from section 210.3 to apply to part 201, it would have been included in this list. But the Seventh Circuit has repeatedly observed that "*expressio unius* has reduced force in the context of interpreting agency administered regulations." *Exelon Generation Co. v. Loc. 15, Int'l Bhd. of Elec. Workers, AFL-CIO*, 676 F.3d 566, 571 (7th Cir. 2012) (alterations accepted) (internal quotation marks omitted), *as amended* (May 9, 2012); *White v. United Airlines, Inc.*, 987 F.3d 616, 622 (7th Cir. 2021) ("[W]e are loath to place as much weight as United does on the *expressio unius* canon, which we have characterized as much-derided and disfavored.") (internal quotation marks omitted). Although Barnes argues that the listed parts all relate to manufacturing, rather than labeling, she does not explain why this distinction is significant. Both parts are within the same subchapter

regulating drugs, and 21 C.F.R. § 210.3(b)(3) provides the only definition of "component" within the subchapter. *Cf. Belom v. Natl. Futures Ass'n*, 284 F.3d 795, 798 (7th Cir. 2002) ("We can assume that Congress intended the same terms used in different parts of the same statute to have the same meaning.").

Moreover, there is evidence that rebuts the application of the *expressio unius* canon in this case. The definition of "inactive ingredient" from 21 C.F.R. § 201.66 was added after 21 C.F.R. § 210.3 was codified. *See* Over-The-Counter Human Drugs; Labeling Requirements, 64 Fed. Reg. 13254, 13258 (Mar. 17, 1999). In adding the "inactive ingredient" definition, the preamble to the final rule states that the definition "is identical to the definition in the agency's good manufacturing practice regulations in 21 CFR 210.3(b)(8)." *Id.* Because the FDA notes that the definitions are identical, it follows that the term "component" used in both definitions was intended to have the same meaning.

Having concluded that the FDCA does not require Unilever to have listed benzene on its product label, the question remains whether Barnes's deceptive practices claims based on this alleged omission are preempted under 21 U.S.C. § 379r(a).

Turek v. General Mills, Inc., 662 F.3d 423, 427 (7th Cir. 2011), addressing a similar express preemption provision in the FDCA relating to food labeling, is illustrative. The plaintiff in *Turek* argued that the labeling of Fiber Plus bars was misleading for omitting that the fiber was from "inulin extracted from chicory root," which allegedly was an inferior form of fiber that could be harmful to some people. *Id.* at 425–26. The Seventh Circuit concluded that the Fiber Plus bars were compliant with FDA regulations

pertaining to the labeling of fiber, which did not require the disclosure of inulin or its health effects. *Id.* at 427. Because "[t]he disclaimers that the plaintiff want[ed] added to the labeling of the defendants' inulin-containing chewy bars [we]re not identical to the labeling requirements imposed on such products by federal law, . . . they [we]re barred." *Id.* "Even if the disclaimers that the plaintiff want[ed] added would be consistent with the requirements imposed by the Food, Drug, and Cosmetic Act, consistency is not the test; identity is." *Id.* Thus, "the FDCA preempt[s] the plaintiffs' attempt to use state law to require that disclosure language be *added* to a food label when federal regulations did not explicitly require it." *Bell v. Publix Super Markets, Inc.*, 982 F.3d 468, 484 (7th Cir. 2020) (citing *id.*).

In this case, to the extent Barnes's deceptive practices claims are based on the alleged omission of benzene from Unilever's products' labels, the claims effectively seek to add the disclosure of benzene on the products' labels where federal regulations do not explicitly require it. Barnes alleges that benzene is a contaminant, not an intended ingredient of the products. *See* Am. Compl. ¶ 58 ("The Products are not designed to contain benzene . . . ."); ¶ 84 ("The Products contain butane as a propellant, which Valisure identified as a potential source of contamination of benzene."); ¶ 86 ("[T]here is high potential for benzene contamination in the processing of butane."). Accordingly, Unilever was not required by the FDCA to disclose the presence of benzene on its products' labels.

Barnes contends that the FDA "specifically alerted drug manufacturers about benzene contamination issues" in its guidance. Pl.'s Resp. Br. at 4. But the guidance Barnes cites in her amended complaint does not mention labeling at all. *See* Q3C -

Tables and List Guidance for Industry, 2017 WL 3491767. Furthermore, the guidance is not legally binding, which the document itself makes clear. *See id.* at *1 ("FDA's guidance documents do not establish legally enforceable responsibilities."). "[B]ecause guidance documents are not binding requirements, mere deviation from their practices will not support a parallel claim." *Lowery v. Sanofi-Aventis LLC*, 535 F. Supp. 3d 1157, 1183 (N.D. Ala. 2021). The applicable regulation, 21 C.F.R. § 350.50, a legally binding regulation on the labeling of antiperspirants, does not require benzene warnings or the labelling of benzene.[3] Thus, to the extent Barnes's deceptive practices claims are based on the alleged omission of benzene from Unilever's products' labels, they are expressly preempted under 21 U.S.C. § 379r(a).

Barnes contends that, similar to her unfair practices claims, her deceptive practices claims based on alleged omissions are "parallel" state law claims because they are identical to FDA's prohibition on misbranded drugs. Pl.'s Resp. Br. at 3–4. This contention "rests on a mistaken premise." *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 376 (S.D.N.Y. 2014); *see also Harris v. Topco Assocs., LLC*, 538 F. Supp. 3d 826, 831 (N.D. Ill. 2021) (rejecting the same argument because it "misses the points of preemption . . . as her claims are based on the labeling of the products themselves, not on a legal theory"). Unlike Barnes's unfair practices claims based on Unilever's sales of adulterated products, which were supported by Unilever's alleged

[3] Neither does the most recent monograph on antiperspirants cited by Barnes. *See* Over-the-Counter (OTC) Monograph M019: Antiperspirant Drug Products for Over-the-Counter Human Use (November 23, 2021), available at https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M019-Antiperspirant%20Drug%20Products%20for%20OTC%20Human%20Use%2011.23.2021.pdf.

violations of the FDA's manufacturing regulations, her deceptive practices claims allege that Unilever's products are misbranded despite Unilever's *compliance* with the FDA's labeling regulations. *See Bausch*, 630 F.3d at 552 (holding that a similar preemption provision "protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law."). The FDA's regulations permit the exclusion of unintended ingredients from the product's label, therefore, adhering to these regulations would not violate the FDCA's general prohibition against misbranded drugs. For Barnes to succeed on her claim that Unilever fraudulently omitted the presence of benzene, state law would impose the requirement that Unilever must disclose the presence of benzene, contrary to the federal regulations. This is what 21 U.S.C. § 379r(a) prohibits. *See Bowling*, 65 F. Supp. 3d at 376 ("If successful, this litigation would do exactly what Congress, in passing section 379r of the FDCA, sought to forbid: using state law causes of action to bootstrap labeling requirements that are 'not identical with' federal regulation.").

Reid v. GMC Skin Care USA Inc., No. 8:15-CV-277-BKS-CFH, 2016 WL 403497, at *10 (N.D.N.Y. Jan. 15, 2016), relied upon by Barnes, is not applicable to her omission allegations. In *Reid*, the plaintiffs alleged that the products did not work as advertised. The court held that "because the FDCA does not regulate the use of efficacy claims on drug and cosmetic labeling, their claims are not preempted." *Id.* "[C]ourts have held that claims that a defendant misrepresented the effectiveness of its product are traditional claims of consumer misrepresentation, not an attempt to enforce the FDCA's labeling requirements." *Id.* (alterations accepted) (internal quotation marks omitted).

Barnes's deceptive practices claim based on omissions alleges that Unilever's product was mislabeled because it failed to disclose the presence of benzene, not that its antiperspirant was not as effective as the labeled claimed.

Barnes also relies on *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. MDL 2875 (RBK-JS), 2020 WL 7418006, at *7-9 (D.N.J. Dec. 18, 2020), for the proposition that the "failure to disclose [the] presence of [a] carcinogen [is] not preempted by the FDCA." Pl.'s Resp. Br. at 4. But the drug at issue in *Valsartan* was a prescription drug, not an OTC drug, which is significant because there is no express preemption provision relating to prescription drugs. *See Wyeth*, 555 U.S. at 567. Thus, the court instead considered and rejected "impossibility" and "unacceptable obstacle" conflict preemption arguments, which are not at issue in this case. *Valsartan*, 2020 WL 7418006, at *8. *Valsartan* is accordingly inapplicable.

Lastly, Barnes contends that nothing prohibits Unilever from including an additional warning of benzene and its effects on the label, citing FDA regulations that require the labeling of "serious warnings." Pl.'s Resp. Br. at 5 (citing 21 C.F.R. § 201.57(c)(1); 21 C.F.R. § 314.70(c)(6)(iii)(A)). But those regulations apply to prescription drugs, not OTC drugs. Specifically, 21 C.F.R. § 201.57 states that "[t]he requirements in this section apply only to prescription drug products." In each case Barnes cites to support her argument, the court analyzed conflict preemption, holding that there was not "clear evidence" that the FDA would have prohibited additional warnings sought by the plaintiffs, and therefore that it was not "impossible" for the defendants to have complied with both state and federal law. *See Wyeth*, 555 U.S. at 568–73; *Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2012 WL 39793, at

*4–8 (N.D. Ill. Jan. 9, 2012); *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1018, 1031–33 (S.D. Ill. 2001). As stated above, that is not the applicable analysis in this case because of the express preemption provision.

In sum, Barnes's deceptive practices claims based on alleged omissions on Unilever's products' labels are expressly preempted. Barnes's deceptive practices claims based on alleged affirmative misrepresentations, however, are not preempted. The statements on Unilever's website concern product safety and testing, *see* Am. Compl. ¶ 94, which do not implicate Unilever's preemption arguments applying the FDA's labeling requirements. Therefore, the Court dismisses Barnes's deceptive practices claims only to the extent they are based on alleged omissions, not affirmative misrepresentations.

Unilever also argues that Barnes's "ICFA claim—to the extent it is based on benzene not being listed as an ingredient on the Suave Product label—is precluded by ICFA's Safe Harbor provision." Def.'s Opening Mem. at 8; *see* 815 Ill. Comp. Stat. 505/10b(1) ("Nothing in this Act shall apply to . . . [a]ctions or transactions specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of this State or the United States . . . ."). Because the Court has already determined that Barnes's ICFA claim based on the alleged omission of benzene from Unilever's products' labels is expressly preempted, the Court need not reach this argument.[4]

[4] Unilever does not appear to extend its safe harbor argument beyond Barnes's "labeling-based" ICFA claim. Def.'s Reply Br. at 6. Even if Unilever had contended that Barnes's unfair practices ICFA claim was precluded under the safe harbor, the argument would fail because Unilever's alleged unfair conduct, i.e., its sales of adulterated drugs, are not "specifically authorized" by the FDA, nor does Unilever argue

C. Bogdanovs's equitable claims

Lastly, Unilever contends that Bogdanovs's claims for equitable relief must be dismissed because she has not alleged that legal remedies would be inadequate as required under Ninth Circuit precedent. *See Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 841-44 (9th Cir. 2020). "Courts in the Ninth Circuit are divided on how exacting of a standard *Sonner* imposes on plaintiffs who plead claims for equitable and legal remedies at the pleading stage." *Jeong v. Nexo Fin. LLC*, No. 21-CV-02392-BLF, 2022 WL 174236, at *27 (N.D. Cal. Jan. 19, 2022) (holding that equitable and legal remedies can be alleged in the alternative).

Bogdanovs alleges in the amended complaint that "Bogdanovs and California Subclass Members have no adequate remedy at law for this claim," and that "legal remedies available to Plaintiff Bogdanovs are inadequate because they are not 'equally prompt and certain and in other ways efficient' as equitable relief." Am. Compl. ¶¶ 205-206 (quoting *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937)). At the pleading stage, these allegations are sufficient to allege that legal remedies are inadequate. *See Murphy v. Olly Pub. Benefit Corp.*, No. 22-CV-03760-CRB, 2023 WL 210838, at *11 (N.D. Cal. Jan. 17, 2023) (holding that the allegation that "legal remedies were not as certain as equitable remedies" was sufficient to allege that plaintiffs lacked an adequate legal remedy). Moreover, Bogdanovs contends that she lacks an adequate remedy at law for her allegations that Unilever violated the California Sherman Act, which is the basis of her unlawful practices CUCL claim. *See Elgindy v.*

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that they are. *See Vanzant*, 934 F.3d at 738 (holding that ICFA's safe harbor provision does not apply where the defendant's alleged sales of adulterated products were not specifically authorized).

AGA Serv. Co., 20-CV-06304-JST, 2021 WL 1176535, at *15 (N.D. Cal. Mar. 29, 2021) (holding that where the "Plaintiffs' claims under the unlawful and unfair prongs of the UCL [we]re rooted in a different theory than Plaintiffs' common-law fraud, FAL, and UCL fraudulent prong claims," the plaintiffs were "entitled to pursue equitable relief under this theory"). The Court accordingly declines to dismiss Bogdanovs's claims for equitable relief under the CUCL, CFAL, and CCLRA.

Conclusion

For the reasons stated above, the Court denies defendant's motion to dismiss, except to the extent plaintiffs' claims are based on the alleged omission of benzene on Unilever's products' labels [dkt. no. 65]. The parties are directed to confer and attempt to agree on a schedule for discovery and pretrial proceedings and are to file a joint status report with a proposed schedule by no later than March 20, 2023. A telephonic status hearing is set for March 27, 2023 at 9:00 a.m., using call-in number 888-684-8852, access code 746-1053.

MATTHEW F. KENNELLY
United States District Judge

Date: March 11, 2023